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# DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

December 22, 2020

# Welcome

December 22, 2020

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Associate Commissioner | Laboratory & Infectious Disease Services Division

# Discussion Topics

- COVID-19 Vaccine Updates
- COVID-19 Vaccine Distribution, Allocation & Timeline
- COVID-19 Vaccine Dashboard



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# COVID-19 Vaccine Update



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# Moderna COVID-19 Vaccine

## Authorized Use

- Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 1 (SARS-CoV-2) in individuals 18 years of age and older.



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# Moderna COVID-19 Vaccine Ingredients

- The Moderna COVID-19 Vaccine contains the following ingredients:
  - messenger ribonucleic acid (mRNA)
  - Lipids
    - SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], Cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]
  - Tromethamine
  - Tromethamine hydrochloride
  - Acetic acid
  - Sodium acetate
  - Sucrose



# mRNA-1273 Shipping, Storage and Administration

## Shipping

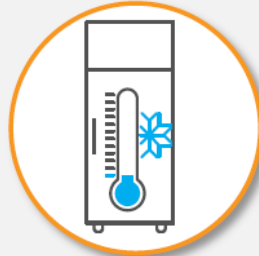
-20°C (-40°C to -15°C)



Able to ship a single  
carton  
(100 doses)

## Local Storage Options

(up to the Date of Expiration)



### Freezer

-15 to -25° C



### Refrigerator

2 to 8°C  
up to 30 days



### Room Temperature

up to 12 hours

Local transportation under  
controlled condition at 2 to 8°C

## Administration



Multiple-dose vial

Use within 6 hours  
after first entry

No dilution required



# Moderna COVID-19 Vaccine Storage

## Storage Prior to Use

- The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). **Store in the original carton to protect from light.**
- Do not store on dry ice or below -40°C (-40°F).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. **Do not refreeze once thawed.**

## Storage After First Puncture of the Vaccine Vial

- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F).
- **Discard vial after 6 hours. Do not refreeze.**



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# Moderna COVID-19 Vaccine

## Dose Preparation & Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake** . Do not dilute the vaccine.
- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on D-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.
- Administer the Moderna COVID-19 vaccine intramuscularly.



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# Moderna COVID-19 Vaccine

## Storage & Handling

### EMERGENCY USE AUTHORIZATION

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

### Frozen Storage

Can be stored frozen until expiration date\*

$-25^{\circ}$  to  $-15^{\circ}\text{C}$  ( $-13^{\circ}$  to  $5^{\circ}\text{F}$ )

Do not store on dry ice or below  $-40^{\circ}\text{C}$  ( $-40^{\circ}\text{F}$ ).  
Store in the original carton to protect from light.

\*Confirm vaccine expiration date by looking up the lot number at [modernatx.com/covid19vaccine-eua](https://www.modernatx.com/covid19vaccine-eua)

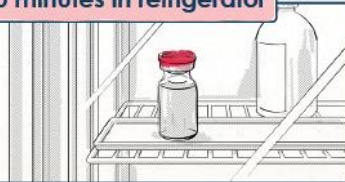


### Thaw Each Vial Before Use

Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

$2^{\circ}$  to  $8^{\circ}\text{C}$   
( $36^{\circ}$  to  $46^{\circ}\text{F}$ )



OR

1 hour at room temperature

$15^{\circ}$  to  $25^{\circ}\text{C}$   
( $59^{\circ}$  to  $77^{\circ}\text{F}$ )



Let vial sit at room temperature for 15 minutes before administering

### Thawed Shelf Life

Unpunctured Vial

Maximum times

30  
days

Refrigerator

$2^{\circ}$  to  $8^{\circ}\text{C}$  ( $36^{\circ}$  to  $46^{\circ}\text{F}$ )

12  
hours

Cool storage up to  
room temperature

$8^{\circ}$  to  $25^{\circ}\text{C}$  ( $46^{\circ}$  to  $77^{\circ}\text{F}$ )



After First Dose Has Been Withdrawn

Maximum time

6  
hours

Refrigerator or  
room temperature

Vial should be held between  
 $2^{\circ}$  to  $25^{\circ}\text{C}$  ( $36^{\circ}$  to  $77^{\circ}\text{F}$ ). Record the date  
and time of first use on the vial label.

Discard punctured vial after 6 hours.



**NEVER** refreeze thawed vaccine

# Moderna COVID-19 Vaccine

## Dosing & Schedule

- The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.
- **Per the guidance from the FDA and the CDC, use every available dose per vial. DO NOT mix partial doses from different vials.**
  - Further guidance coming from the CDC on ordering additional ancillary supplies.
- There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series.
- Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.



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# Moderna COVID-19 Vaccine

## Warning - Management of Acute Allergic Reactions

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.
- Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines.
  - All vaccine recipients be observed for 15 minutes after vaccination.
  - Person with a history of anaphylaxis, due to any cause, be observed for 30 minutes after vaccination.



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# Moderna COVID-19 Vaccine

## Pregnancy

### Pregnancy Exposure Registry

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866- MODERNA (1-866-663-3762).



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# Moderna COVID-19 Vaccine

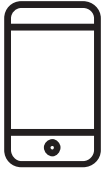
## Mandatory Provider Requirements for Administration under EUA

- Provider must provide to the individual receiving the vaccine the “Fact Sheet for Recipients and Caregivers” prior to vaccination.
- Must report doses administered in ImmTrac2 within 24 hours post vaccination
  - **Report complete information including race/ethnicity**
- Provider must report the following to the Vaccine Adverse Event Reporting System (VAERS): <https://vaers.hhs.gov/reportevent.html>
  - Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events\* (irrespective of attribution to vaccination),
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
  - Cases of COVID-19 that result in hospitalization or death.



# Additional Vaccine Safety Monitoring

## ***v-safe** / after vaccination health checker*



**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.



Vaccine recipients can quickly tell the CDC if they have any side effects. The CDC may follow up with them by phone to get more information.



**V-safe** will also remind them to get their **second COVID-19 vaccine dose**, if needed.



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.





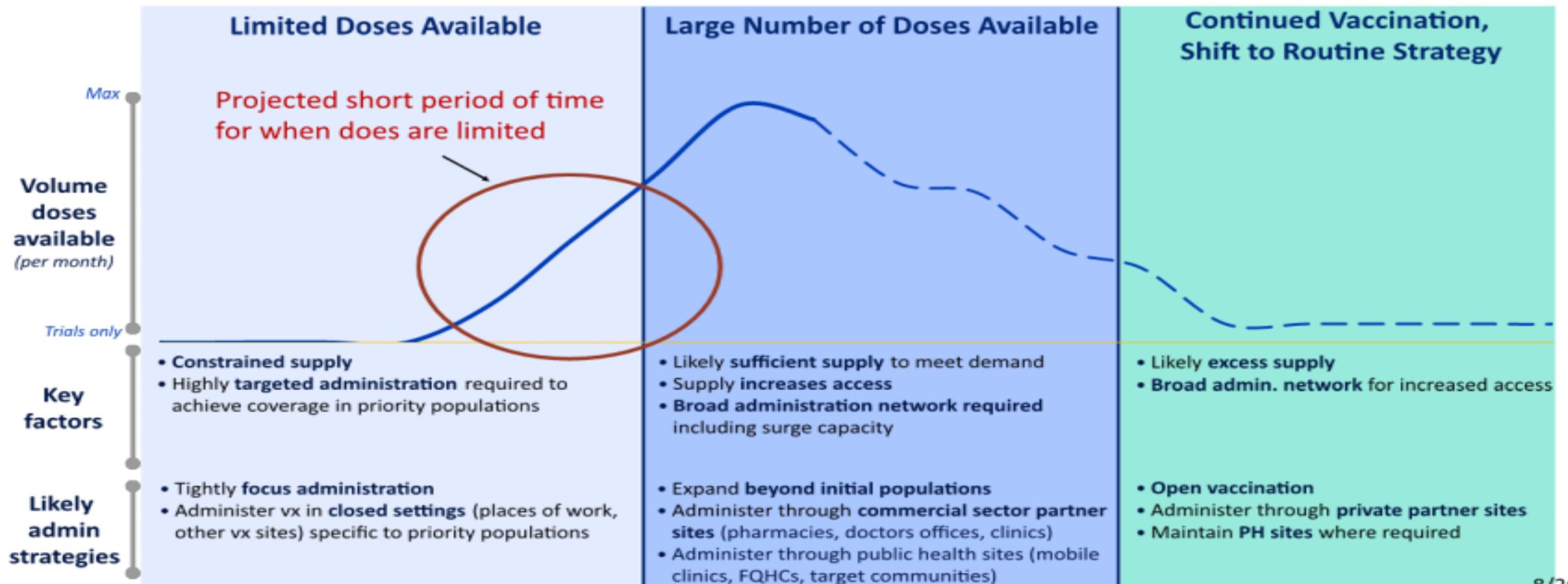
# COVID-19 Texas Vaccine Distribution, Allocation & Timeline



# Phases and Timeframe of COVID-19 Vaccine Distribution

*Draft – for planning purposes only and subject to change*

## Administration of COVID-19 vaccine will require a phased approach



# COVID-19 Vaccine Vaccination Phased-Approach Overview\*

- Phase 0 (September 2020-November 2020)
- Phase 1 (December 2020 – January 2020)
  - Limited COVID-19 Vaccine Doses Available
- Phase 2 (February 2021-July 2021\*)
  - Large Number of Doses Available
  - Supply Likely to Meet Demand
- Phase 3 (July 2021 -October 2021\*)
  - Sufficient Supply



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*\*Specific dates are subject to change.*

# Texas Guiding Principles

- **Protecting health care workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need it.
- **Protecting front-line workers** who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- **Protecting vulnerable populations** who are at greater risk of severe disease and death if they contract COVID-19.
- **Mitigating health inequities** due to factors such as demographics, poverty, insurance status and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach that considers access in urban and rural communities and in affected ZIP codes.
- **Transparency** through sharing allocations with the public and seeking public feedback.

<https://gov.texas.gov/news/post/governor-abbott-dshs-announce-covid-19-vaccine-distribution-plan>



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# Allocation Key Items

- Organizations must be completely approved.
- Number of healthcare workers is used to guide allocations for this Phase 1A.
- Doses administered is being considered for sites already receiving vaccine.



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# COVID-19 Critical Population

## Phase 1A Healthcare Workers Definition – First Tier

- Paid and unpaid workers in hospital settings working directly with patients who are positive or at high risk for COVID-19. Such as but not limited to:
  - Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.)
  - Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services
  - Others having direct contact with patients or infectious materials
- Long-term care staff working directly with vulnerable residents. Includes:
  - Direct care providers at nursing homes, assisted living facilities, and state supported living centers
  - Physicians, nurses, personal care assistants, custodial, food service staff
- EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport
- Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients
- Residents of long-term care facilities



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# COVID-19 Critical Population

## Phase 1A Healthcare Workers Definition – Second Tier

- Staff in outpatient care settings who interact with symptomatic patients. Such as but not limited to:
  - Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.).
  - Clinical staff providing diagnostic, laboratory, and/or rehabilitation services
  - Non 9-1-1 transportation for routine care
  - Healthcare workers in corrections and detention facilities
- Direct care staff in freestanding emergency medical care facilities and urgent care clinics.
- Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID.
- Public health and emergency response staff directly involved in administration of COVID testing and vaccinations.
- Last responders who provide mortuary or death services to decedents with COVID-19. Includes:
  - Embalmers and funeral home workers who have direct contact with decedents
  - Medical examiners and other medical certifiers who have direct contact with decedents.
- School nurses who provide health care to students and teachers.



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# COVID-19 Critical Population

## Phase 1B Definition

- DSHS will work with vaccine providers and local partners to ensure that people who are 65 and older or have the medical conditions listed below and who also work in front-line and critical industries have access to the vaccine so they will be protected from COVID-19 while on the job.
- Texas equally will strive to ensure vaccine reaches communities with health disparities in accordance with Texas Vaccine Allocation Guiding Principles.



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# COVID-19 Critical Population

## Phase 1B Definition

### Texas Phase 1B Vaccine Priorities

- People 65 years of age and older
- People 16 years of age and older with at least one chronic medical condition that puts them at increased risk for severe illness from the virus that causes COVID-19, such as but not limited to:
  - Cancer
  - Chronic kidney disease
  - COPD (chronic obstructive pulmonary disease)
  - Heart conditions, such as heart failure, coronary artery disease or cardiomyopathies
  - Solid organ transplantation
  - Obesity and severe obesity (body mass index of 30 kg/m<sup>2</sup> or higher)
  - Pregnancy
  - Sickle cell disease
  - Type 2 diabetes mellitus



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# Vaccine Allocations

## Week 1 Allocations

- Only Pfizer-BioNTech COVID-19 vaccine available
  - Minimum order 975 doses
  - Ultra-low frozen temperature storage
- Allocated to hospitals with minimum 1,000 healthcare workers
  - Allocated to 110 hospitals

## Week 2 Allocations

- 159,900 doses Pfizer-BioNTech COVID-19 vaccine available for allocation
  - 124,800 reserved for federal pharmacy partnership for Long-Term Care (LTC) Program
    - LTC start date December 28, 2020
- 460,500 doses of Moderna COVID-19 vaccine available for allocation
  - Minimum order 100 doses
  - Stored frozen (6 months), refrigerated 30 days
  - Allocated to diverse provider types



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# Long-term Care Planning

- The start of the Federal LTCF program will be on December 28th, 2020 with major pharmacy chains.
- Work continues to identify the gap of LTC facilities that did not enroll in the federal program and may need state assistance. Likely this work would begin mid-January 2021



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# COVID-19 Vaccine Dashboard

Vaccine Data tab found on [www.dshs.texas.gov/coronavirus/](http://www.dshs.texas.gov/coronavirus/)



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# COVID-19 Vaccination in Texas

DSHS is partnering with vaccine providers across the state to ensure vaccine will be accessible to all Texans at no cost.

Dashboard updated around 4 p.m. each day with data as of 11:59 the previous night.

See the About the Data tab for more information on data sources.



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## Vaccination of frontline and vulnerable populations

COVID-19 vaccination is currently available only to frontline and vulnerable populations due to limited supply. Texas will move through several phases to ensure those who need the vaccine most receive it first. We need every Texan's help to make this a success.

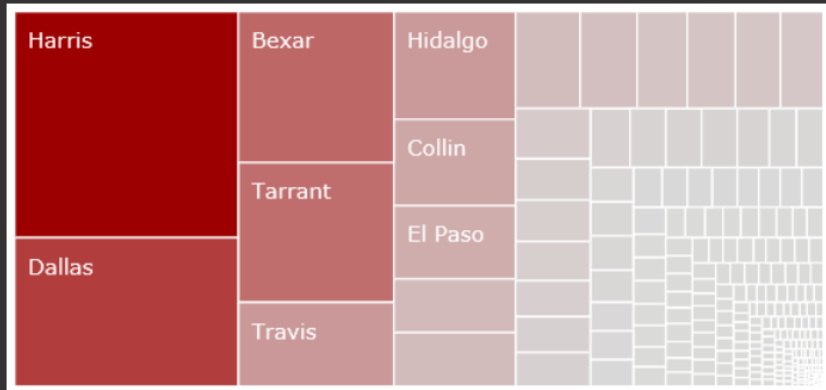
Choose population groups from the list below to see them by county in the red boxes by county.

### Population Group - Phase 1A

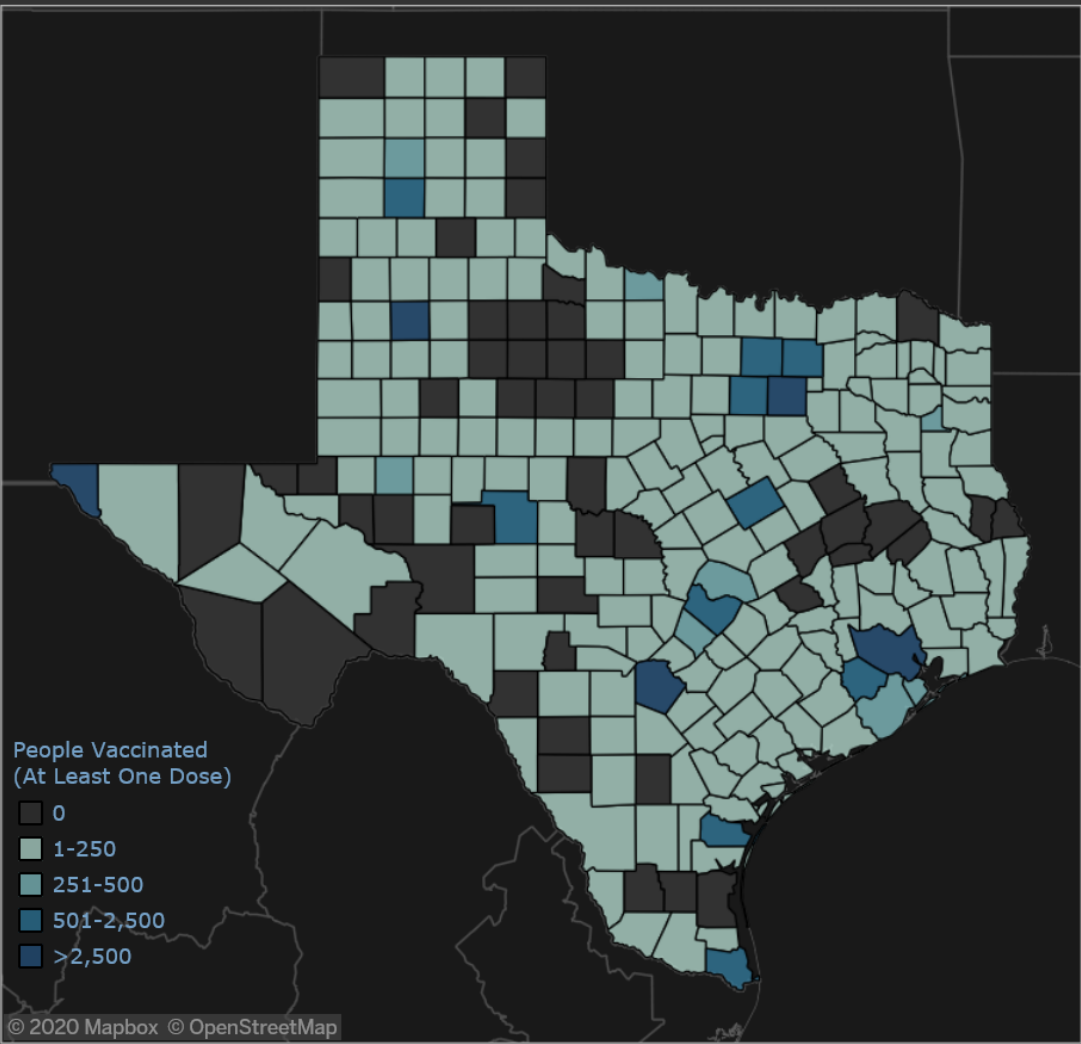
- ☒ (All)
- ☒ Healthcare - Tier 1 (such as hospitals and EMS)
- ☒ Healthcare - Tier 2 (such as medical offices)
- ☒ Long-term Care - Assisted Living Residents/Other
- ☒ Long-term Care - Nursing Home Residents

Visit the DSHS COVID-19 Vaccine Information page for more details on phases and tiers, and other vaccine info:  
<https://www.dshs.texas.gov/coronavirus/immunize/vaccine.aspx>

## Population Groups by County



## Texans Vaccinated for COVID-19



People Vaccinated with at least  
One Dose

42,248

People Fully Vaccinated

0

Doses Received by a Vaccine  
Provider

224,250

Doses Administered

42,248

203 of 254

Counties with Vaccine Doses  
Administered

Last Updated  
12/21/2020 4:16 PM



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## COVID-19 Vaccination in Texas

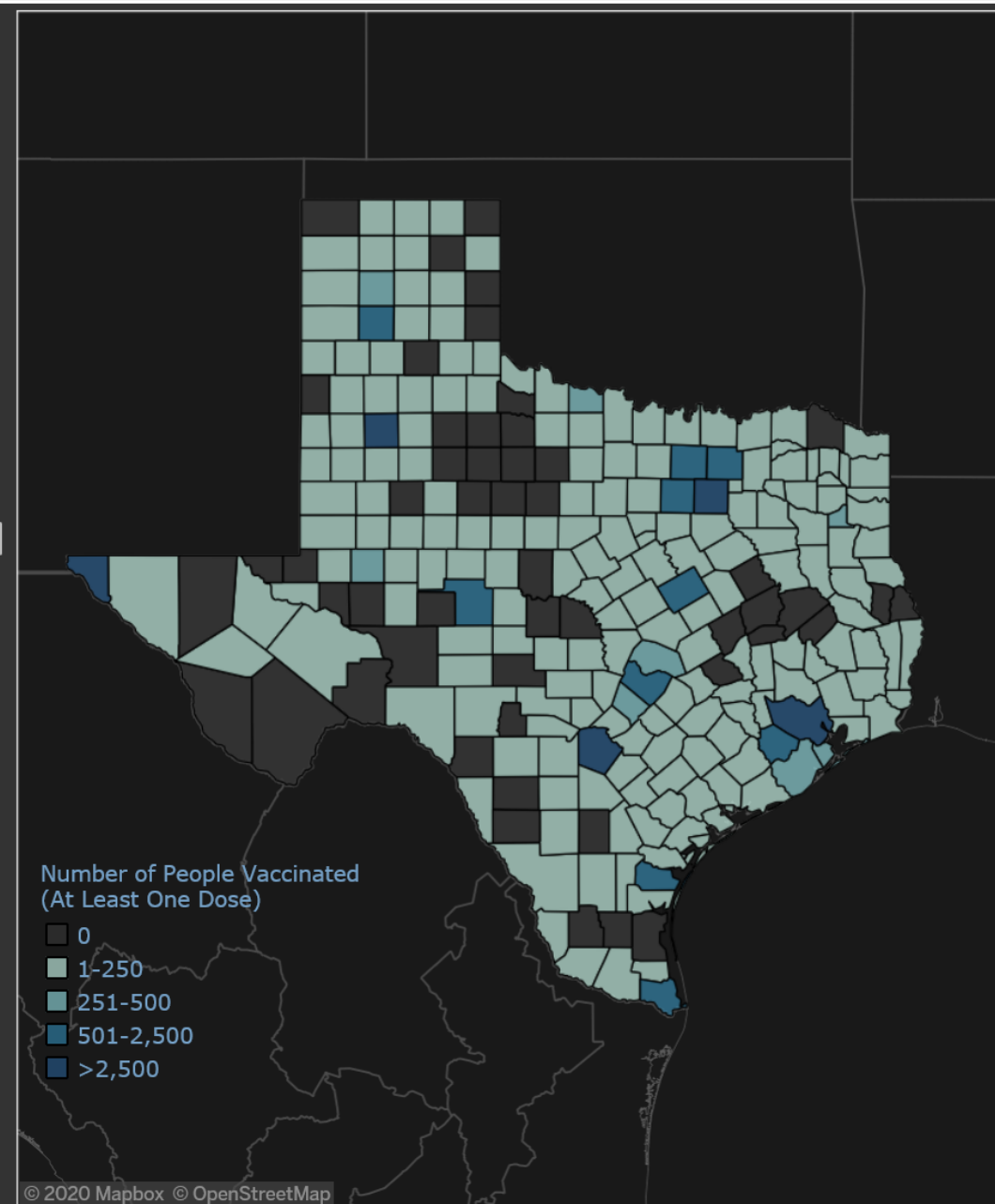
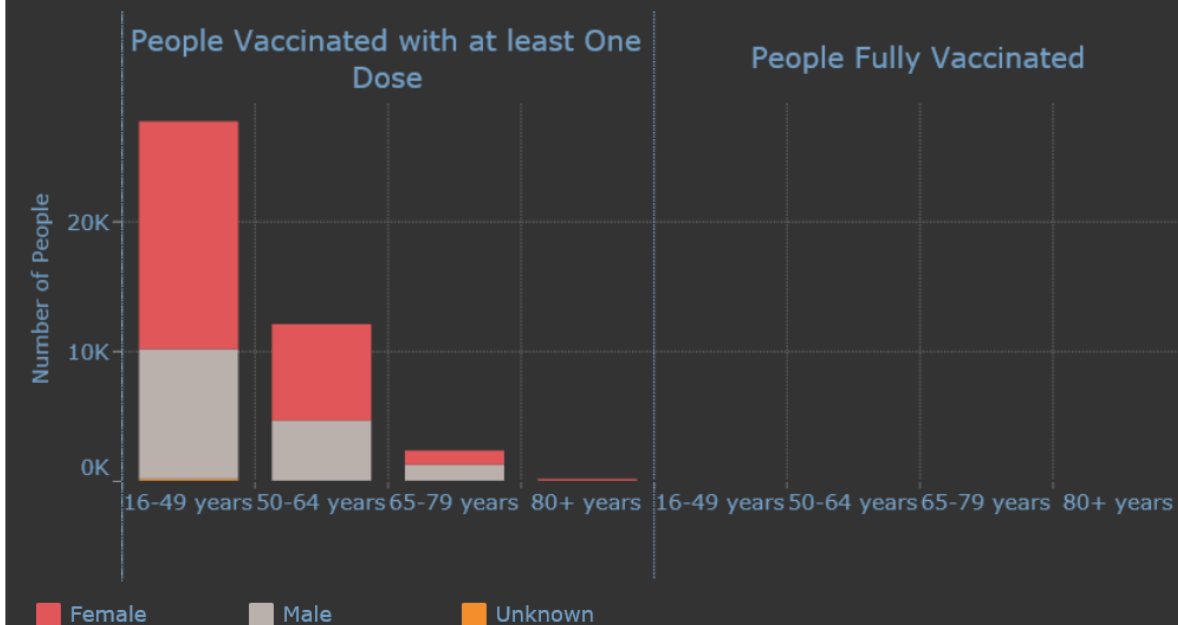
Select a Texas county below to view the number people who have received at least one dose of COVID-19 vaccine and those who have received the number of doses recommended by the CDC (People Fully Vaccinated).

Alternatively, click on a county on the map. Click the Revert button at the bottom of the screen to remove filters.

Search for a County

(All)

## Texans Vaccinated by Age in Texas



Dashboard is updated daily by 4 p.m. CST with data as of 11:59 the previous night.  
For inquiries about the data, email [COVIDVaccineQs@dshs.texas.gov](mailto:COVIDVaccineQs@dshs.texas.gov).

# Key items for Local Engagement

- LHEs should know the locations that received allocations and know circumstances that they are using the vaccine (ID needed, hours, possible local engagement). With this knowledge drive healthcare workers without employer vaccinations to the variety of provider sites.
- LHEs should use the tableau dashboard for visibility on all provider allocations and usage in their jurisdictions.
- **Reminder: only LHEs with an executed data sharing MOU can receive daily ImmTrac2 files on doses administered in their jurisdictions.**
- Engage local leaders and community gatekeepers to assist in messaging and driving healthcare workers to these locations.
- Encourage all providers to report daily to ImmTrac2.

# Important Reminders

- Accept vaccine orders in VAOS.
- Print out Fact Sheet and V-safe documents to give to individuals getting vaccinated.
- Fill out the shot record cards in the ancillary kit supplies.
- Report **daily** all doses administered data to ImmTrac2.
  - **Report complete information including race/ethnicity**
- Vaccinate with **URGENCY**.



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# RESOURCES

## Website for Providers

[www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx](http://www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx)

## FAQ for Providers

[https://www.dshs.texas.gov/immunize/covid19/COVID\\_providerfaq.pdf](https://www.dshs.texas.gov/immunize/covid19/COVID_providerfaq.pdf)

## DSHS COVID-19 Vaccine Provider hotline

(877) 835-7750, 8 a.m. to 5 p.m., Monday - Friday  
Email: [COVID19VacEnroll@dshs.texas.gov](mailto:COVID19VacEnroll@dshs.texas.gov).

## Website to enroll as a COVID-19 provider

[EnrollTexasIZ.dshs.texas.gov](http://EnrollTexasIZ.dshs.texas.gov).

## General Questions

Email: [COVIDvaccineQs@dshs.texas.gov](mailto:COVIDvaccineQs@dshs.texas.gov)

## Vaccine Data Dashboard

[Texans Vaccinated for COVID-19](#) website

## ImmTrac2 support Email

(800) 348-9158, 8 a.m. to 5 p.m., Monday - Friday  
[ImmTrac2@dshs.texas.gov](mailto:ImmTrac2@dshs.texas.gov)

## ImmTrac2 support Email

(800) 348-9158, 8 a.m. to 5 p.m., Monday - Friday  
[ImmTrac2@dshs.texas.gov](mailto:ImmTrac2@dshs.texas.gov)

## V-safe

<https://vsafe.cdc.gov/>  
<https://espanol.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

## Vaccine Adverse Event Reporting System (VAERS)

<https://vaers.hhs.gov/reportevent.html>

## Moderna (Pregnancy Registry & MedInfo)

[medinfo@modernatx.com](mailto:medinfo@modernatx.com)  
1-866- MODERNA (1-866-663-3762)  
[www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua)

## CDC McKesson

Pfizer #: 833-272-6634, Moderna #: 833-343-2703

## Pfizer Medical Information

Visit [PfizerMedicalInformation.com](http://PfizerMedicalInformation.com)  
Call [1-800-438-1985](tel:1-800-438-1985).

# Q & A



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